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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,195	08/03/2001	Rosely M. Zancoppe-Oliveira	65798	3262

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CENTERS FOR DISEASE CONTROL
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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,195

Applicant(s)

ZANCOPE-OLIVEIRA ET AL.

Examiner

Mark Navarro

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,7,10-17,19,21-32 and 3448 is/are pending in the application.
- 4a) Of the above claim(s) 10-15,21-30 and 34-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,6,7,16,19,31,32 and 45-48 is/are rejected.
- 7) ☒ Claim(s) 2,3 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 14, 2004 has been entered.

Claims 4, 5, 8, 9, 18, 20, 33 and 49 have been canceled. Accordingly, claims 1-3, 6-7, 10-17, 19, 21-32, 34-48 are pending in the instant application, of which claims 10-15, 21-30, and 34-44 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1, 6, 7, 16, 19, 31, 45-48 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicants are asserting that the specification has defined the term "H. capsulatum M antigen specific" as "unique to the fungus H. capsulatum as used herein in relation to a nucleic acid or nucleic acid fragment means a nucleic acid or nucleic acid fragment which is not common to other related fungi or other microorganisms (i.e., it is only present in the fungus H. capsulatum)." Applicants further assert that a fragment of

a molecule is, by definition, a subpart of that molecule. Applicants assert that there is no basis to assert that the genus of fragments of SEQ ID NO: 1 is not fully described.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the specification has defined the term "H. capsulatum M antigen specific" as "unique to the fungus H. capsulatum as used herein in relation to a nucleic acid or nucleic acid fragment means a nucleic acid or nucleic acid fragment which is not common to other related fungi or other microorganisms (i.e., it is only present in the fungus H. capsulatum)." However, aside from SEQ ID NO: 1, Applicants have not provided any other structures which would enable one of skill in the art to recognize the claimed genus, i.e., any fragment of SEQ ID NO: 1 "comprising" additional nucleotides upstream and/or downstream of this fragment having potentially radically distinct structures and functions. While the specification provides sufficient written description for the structure of SEQ ID NO: 1 and for fragments "consisting of" SEQ ID NO: 1, one of skill simply would not recognize the broadly claimed genus of fragments "comprising" short stretches of this sequence with divergent upstream and downstream regions.

Finally, Applicants further assert that a fragment of a molecule is, by definition, a subpart of that molecule and that there is no basis to assert that the genus of fragments of SEQ ID NO: 1 is not fully described. However, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted (e.g., short

segments of SEQ ID NO: 1 “comprising” numerous divergent upstream and downstream regions). Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a “H. capsulatum M antigen-specific fragment” is insufficient to describe the genus.

Claims 1, 6, 7, 16, 19, 31, and 45-48 recite an H. capsulatum M antigen-specific fragment as well as fragments having a percent identity to SEQ ID NO: 1.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a “H. capsulatum M antigen-specific fragment” alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed.” The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.”

Applicant is reminded that Vas-Cath make clear that the written description provision of

35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a **representative number** of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.” (Emphasis added).

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 “Written Description” Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 1, 4-5, 8-9, 16, 18, 20, 31 and 33 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of “substantially the same” is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 1-3, 6-7, 16-17, 19, 31-32, and 45-48 under 35 U.S.C. 102(a) as being anticipated by Zancoppe-Oliveria et al is withdrawn in view of Applicants arguments.
4. The rejection of claims 1 and 4-9 under 35 U.S.C. 102(b) as being anticipated by Stryer et al is withdrawn in view of Applicants amendments.
5. The rejection of claims 1 and 4-9, 16, 18-20, 31, 33, and 45-49 under 35 U.S.C. 102(e) as being anticipated by Lee et al is withdrawn in view of Applicants amendments.

The following new grounds of rejection are applied to the claims:

Claim Objections

6. Claims 16 and 31 are objected to because of the following informalities: Claim 16 recites "or" followed by "and" in presumably non-intended order. Likewise claim 31 ends with the word "or." Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 31-32 are rejected under 35 USC 101 as the claimed invention is directed to non-statutory subject matter.

Applicants specification contemplates mammalian host expression systems. (Page 31). This can encompass cloned human cell lines, which is a non-statutory invention. Amendment of the claim to recite "isolated host cell" will be sufficient to overcome this rejection.

Claims 2-3 and 17 are objected to for depending upon a rejected base claim, however claims 2-3 and 17 are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. The examiner can normally be reached on 5/4/9.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
May 9, 2005